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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
PERKINS, S	
ART UNIT	**PAPER NUMBER**
1811	2

DATE MAILED: 10/29/91

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined for restriction purposes only. ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-46 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-46 are subject to restriction or election requirement.
7. ☑ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15. Claims 1-46 are pending in this application.

16. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 6, 11-19, 39, 40, and 46, drawn to Urinary Tumor Associated Antigen (UTAA), epitopes thereof, and vaccines containing the antigens, classified in Class 530 and 424, subclasses 350 and 88, respectively.

II. Claims 2 and 5, drawn to monoclonal antibodies of UTAA, classified in Class 530, subclass 387.

III. Claims 30-34, drawn to nucleic acid encoding UTAA, classified in Class 536, subclass 27.

IV. Claims 22-25, drawn to radio-imaging, classified in Class 424, subclass 1.1.

V. Claims 3, 4, 9, 10, 20, 21, 35-38, and 41-45, drawn to methods of detecting or monitoring cancer, classified in Class 435, subclass 7.

VI. Claims 6, and 7 drawn to anti-idiotypic antibodies which react with antibodies of UTAA, classified in Class 530, subclass 387.

VII. Claim 8, drawn to immunotherapy using anti-idiotypic antibodies which react with antibodies of UTAA, classified in Class 424, subclass 85.8.

VIII. Claims 26-29, drawn to a method of inhibiting a tumor expressing UTAA, classified in Class 424, subclasses 85-91.

17. The inventions are distinct, each from the other because of the following reasons:

18. Group I (urinary tumor associated antigen, UTAA), Group II (monoclonal antibodies to UTAA), and Group VI (anti-idiotypic antibodies) are each drawn to independent and distinct inventions. Each of these compositions are structurally and functionally unique and each have their own utilities. Moreover, each Group raises different issues of patentability and the search for one is not co-extensive of a search for the other.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

19. Group I (urinary tumor associated antigen, UTAA) and Group III (nucleic acid) are each drawn to independent and distinct inventions. Each of these compositions are structurally and functionally unique and each have their own utilities. For example the nucleid acid can be used for probes and the antigen for vaccine purposes. Moreover, each Group raises different issues of

patentability and the search for one is not co-extensive of a search for the other.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

20. Inventions of Group II (monoclonal antibodies to UTAA) and Group IV (radio-imaging) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as in the detection and monitoring of cancer.

21. Inventions Group II (monoclonal antibodies to UTAA) and Group V (methods of detecting and monitoring cancer) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as inhibiting a tumor expressing UTAA.

22. Inventions of Group II (monoclonal antibodies to UTAA) and Group VIII (method of inhibiting a tumor expressing UTAA) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as radio-imaging in vivo.

23. Inventions of Group VI (anti-idiotypic antibodies) and Group VII (immunotherapy using anti-idiotypic antibodies) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as for diagnostic purposes or for purification and identification of cellular receptors.

24. This application contains claims directed to the following patentably distinct species of the claimed invention: various UTAA and epitopes thereof. The patentably distinct species are an antigenic polypeptides of UTAA having molecular weights of 45, 65,

90-100 and 120 kD subunits. **If Applicant elects Group I (UTAA and vaccines), Applicant should further elect an ultimate election of specie of antigenic polypeptide of UTAA (e.g. subunit that is 45 kD, or subunit that is 65 kD, etc.).**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

25. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown

by their divergent classification and divergent subject matter, restriction for examination purposes as indicated is proper.

26. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

27. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 1811.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Susan Perkins whose telephone number is (703)-308-1030. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)-308-0196.

S.M.Perkins
10-28-91

HOWARD E. SCHAIN
PATENT EXAMINER
GROUP 180-ART UNIT 186

Howard E. Schain